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Manuscript Draft

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Title: Evaluation of nutrition assessment tools compared with body cell mass for the assessment of malnutrition in chronic kidney disease

Article Type: Original Research

Keywords: Nutrition Assessment; Chronic Kidney Disease; Subjective Global Assessment; Body Cell Mass; Nutritional Status

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Abstract: Objective: To compare the Subjective Global Assessment (SGA) and a range of SGA-based assessment tools with body cell mass in Stage IV and V pre-dialysis chronic kidney disease (CKD) patients.

Study design: Cross-sectional, observational.

Setting: Public tertiary hospital pre-dialysis outpatient clinic

Patients: Fifty-six consecutive consenting CKD patients (male 61%; age (mean \pm SD) 70.2 \pm 11.6 years; GFR(MDRD) 22.2 \pm 6.8 ml/min).

Main Outcome measure: Nutrition status.

Results: In this population the prevalence of malnutrition was 19.6% (n=11, SGA B; no C ratings).

Malnutrition was associated with lower body cell mass (mean BCM, 26.3 vs. 33.4 kg p=0.007, measured by total body potassium, TBK), body weight (64.8 vs. 76.1 kg p=0.042), BMI (23.7 vs. 27.6 kg/m² p=0.015) and

greater weight loss over previous 6 months (-6.2 vs. -0.1 kg $p=0.004$). Body cell mass had a weak relationship with 7-point SGA ($p=0.267$), malnutrition inflammation score (MIS $r=-0.27$ $p=0.063$) and patient-generated SGA (PG-SGA $r=-0.27$ $p=0.060$). There was no association for either measure of nutrition status (SGA or BCM) with albumin, glomerular filtration rate or C-reactive protein.

Conclusion: SGA in its original form most accurately delineated malnutrition by depleted BCM and is the most appropriate tool for cross-sectional assessment of nutrition status in predialysis CKD patients.

30 March 2006

Editor, *Journal of Renal Nutrition*
C/O Elsevier Publishing

Dear Editor,

Please find enclosed an electronic submission of our manuscript entitled **“Evaluation of nutrition assessment tools compared with body cell mass for the assessment of malnutrition in Stage IV chronic kidney disease”** for your consideration for publication in *Journal of Renal Nutrition*.

This is an original research article investigating a range of clinical nutrition assessment measures compared with body cell mass (BCM) in a cohort of Stage IV Chronic kidney disease patients. This investigation highlighted the diagnostic ability of the Subjective Global Assessment (SGA), as it was the tool that most accurately delineated malnutrition by depleted BCM, and is therefore considered the most appropriate tool for cross-sectional assessment of nutrition status in Stage IV CKD. With an increasing number tools available for clinicians, this paper is thought to be topical, timely and of relevance to *Journal of Renal Nutrition* readership to build the evidence-base for nutrition assessment measures in CKD.

The content of this paper is original and has not been published or submitted for publication elsewhere.

I look forward to further communication.

Yours sincerely,

Katrina L Campbell

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Reviewer #1:

1) In the conclusion of the abstract after SGA add "in its original form".
Completed

2) Pg 6, last paragraph of the results section, line 3, delete "and approached statistical significance when correlated with BCM". Since MIS and PG-SGA reached a borderline statistical significance ($P=0.06$) and the 7-point SGA showed no association when correlated with BCM.
Completed

3) Pg 8, change is to was after "the second objective of this study"
Completed

4) Pg 9, 2nd paragraph, line 10 add the word borderline before "statistical significance" since it is clearly stated in the method section that only P less than 0.05 would be considered as significant.
Completed

5) Pg 9, 2nd paragraph, line 11, correct the r value -2.7 to -0.27
Completed

6) Figure 1, delete stage IV from the legend.
Completed

Reviewer #2:

Page 2 Background, second paragraph first line is should be was
Completed

Page 4 last line was should be were
Completed

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assessment of malnutrition in chronic kidney disease**

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Evaluation of nutrition assessment tools compared with body cell mass for the assessment of malnutrition in chronic kidney disease

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Key Words: Nutrition Assessment; Chronic Kidney Disease; Subjective Global Assessment; Body Cell Mass; Nutritional Status

Background

A number of tools exist in clinical and research practice in chronic kidney disease (CKD) to measure nutrition status¹. Many of the tools in use are based on the parameters from the Subjective Global Assessment (SGA)^{1,2}. SGA was originally validated in surgical inpatients^{2,3}, and has since displayed similar merits and has gained widespread use in CKD^{1,4-6}. The parameters for assessment include medical history (weight change, dietary intake change, gastrointestinal symptoms, and changes in functional capacity) and physical examination (assessment of subcutaneous fat and muscle mass stores)².

Clinical assessment tools, such as the SGA is just one of a panel of nutrition indicators recommended by the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (K/DOQI)⁴. To date, there appears to be no single method available to clinicians to accurately assess nutrition status in CKD. Clinical tools are potentially valuable in the assessment of malnutrition for benchmarking and evaluating change in nutrition status, without influence from non-nutrition factors.

A recent review of SGA-based nutrition assessment revealed a number of promising tools for use in CKD including 7-point SGA, the semi-objective malnutrition inflammation score (MIS) and Patient-Generated SGA (PG-SGA)⁶. These tools expand the scale of the SGA to a larger number of categories (7-point scale)^{4,7} or provide a continuous score with additional objective nutrition-related information (PG-SGAScore⁸, MIS⁹). A potential benefit of such tools is to improve the ability to measure the degree of malnutrition and to identify small, yet significant changes in

nutrition status¹⁰. To the author's knowledge, there has been no previously published data using these tools in a non-dialysis CKD population.

The aim of this study was to investigate the comparability of the SGA-based clinical assessment tools against the original SGA and total body potassium (TBK), a gold-standard measure for body cell mass (BCM).

Methods

Consecutive patients in a multi-disciplinary pre-dialysis outpatient clinic were approached to participate over a 12-month period (09/2004-08/2005). Eligibility criteria included: ≥ 18 years old, glomerular filtration rate (GFR) estimated by MDRD equation¹¹ ≤ 30 ml/min (and not expected to require dialysis within 3-6 months) and an absence of malnutrition due to diseases other than kidney disease (eg oncology). Of the 64 eligible patients, written consent was obtained from 60 (96% enrolment rate), as per protocol approved by the Royal Brisbane and Women's Hospital and Queensland University of Technology Human Research Ethics committees.

Of the 60 participants recruited and consented, 4 participants did not receive baseline assessment following initial SGA assessment (reached end-point (dialysis or transplantation $n=2$), or voluntary withdrawal ($n=2$) prior to further assessment). Of the final 56 participants (male 61%; (mean \pm SD) age 70.7 ± 11.9 years; GFR_{MDRD} 22.4 ± 6.5 ml/min), 6 were withdrawn from BCM assessment due voluntary withdrawal from TBK ($n=2$), or when participants waist circumference exceeded the limits of the TBK sensor ($n=4$).

Nutrition assessment was conducted simultaneously using subjective global assessment (SGA)² and the more recent modifications of the SGA, 7-point SGA⁷, MIS⁹ and PG-SGA⁸. The 7-point SGA is an expansion of the rating categories for nutrition status of the original SGA, from 3 (A, B and C) to 7 (rating 1 severely malnourished to 7 well nourished)⁷. The MIS scores each of the parameters of the SGA (0-3), and in addition, BMI, albumin and total iron-binding capacity, providing an additive score of 0 to 30⁹. The rating of the MIS was modified in this study from the initial protocol by removing dialysis vintage within the co-morbidity scoring component with permission granted the author (personal communication). PG-SGA assesses a broader range of parameters based on the SGA, focusing on acute changes, scoring each component (0-4), to give an additive score of 0-35, along with the global rating (A,B or C)¹². The assessments were performed by a single dietitian, trained and experienced in using the SGA-based tools, according to the protocol^{2, 9, 12, 13}.

TBK, a gold-standard measure of BCM, blinded to the dietitian, was performed by a shadow shield whole-body counter of the naturally occurring isotope ⁴⁰K (Accuscan; Canberra Industries, Meriden, CT). This isotope represents a fixed proportion of naturally occurring potassium detected by the 1.46-MeV gamma ray emitted by ⁴⁰K. Two 1100-s scans were performed for each subject. All personal metallic objects having been removed; the subject was required to lie supine on a scanning bed that was moved under the detectors. Background and sensitivity checks were completed daily and considered in each measurement. BCM was calculated from TBK by using the equation of Wang et al (2004)¹⁴.

After an overnight fast serum albumin, creatinine and iron studies (including total iron binding capacity) were taken in all participants, and C-reactive protein (standard

method) in 60% of cases (n=33). Analysis of pathology was undertaken at a central laboratory.

Statistical analysis was carried out using SPSS Version 13 (SPSS Inc, Chicago, IL, USA). All continuous variables were tested for normal distribution, CRP and PG-SGA score were the only skewed distributions. Variables were compared against both SGA and BCM. The relationship between the variables and SGA was assessed via chi-square for categorical and t-test or Mann-Whitney U for continuous variables. BCM to the other clinical variables was assessed by t-test and ANOVA for categorical and Pearson or Spearman correlation for continuous variables. Although the MIS was normally distributed, Spearman correlation (non-parametric) was used for consistency in analysis with the PG-SGA score. All results were considered significant if the p-value was less than 0.05.

Results

Table 1 provides an overview of characteristics of participants eligible to participate in this study. There was little difference between the groups. Eligible patients that refused the study (n=4), withdrew from participating (n=4) or participated but did not receive TBK assessment (n=6) were more likely to be female, younger, with lower renal function than the TBK-assessed group. Study participants without TBK had significantly higher body weight/BMI than the TBK-assessed group. The rate of malnutrition was reasonably consistent for all groups (17-25%).

Of the study participants (n=56), 19.6% (n=11) rated moderately malnourished (SGA B; no C ratings) according to SGA. As well as having significantly lower BCM

(mean \pm SD, 26.3 \pm 6.3 vs. 33.4 \pm 7.5kg p=0.007), moderately malnourished patients (SGA B) also had significantly lower body weight (64.8 \pm 20.9 vs. 76.1 \pm 14.6kg p=0.042), BMI (23.7 \pm 4.6 vs. 27.6 \pm 4.5kg/m² p=0.015) and greater weight loss over 6 months (-6.2 \pm 4.3 vs. -0.1 \pm 2.4kg p=0.004) compared with well-nourished (SGA A, Table 2). When this relationship was examined by gender, the trend for lower BCM in the malnourished group remained, however, was only statistically significant for females (25.4 \pm 4.5 vs 22.5 \pm 2.4kg p=0.05; males 36.6 \pm 5.3 vs 34.4 \pm 3.4kg, NS). There appeared to be no association for SGA ratings and BCM with albumin, CRP, renal function or age (Table 2 and 3).

Distribution of the scores (MIS, PG-SGA score) and ratings (7-point SGA) were statistically and clinically significant when compared to the ratings of SGA A and B (Table 4). The relationship for BCM to 7-point SGA (Figure 1) indicates a rise in BCM with lower ratings (from 3 to 5) and plateau in BCM with higher ratings (5 to 7) of nutritional status. Distribution of scoring for the MIS (median (range) 4 (0-12)) and PG-SGA (3 (0-15)) were very similar. Correlations for the relationship of BCM to the two scored tools indicate a weak, yet similarly patterned relationship to BCM (Table 4).

Discussion

Since initial validation of SGA in hemodialysis (HD) patients¹⁵, SGA has been a classification standard of nutritional status in pre-dialysis^{16, 17}, commencing dialysis¹⁸⁻²⁰ and maintenance dialysis^{18, 21-24} populations. This investigation supports the diagnostic ability of the SGA rating scale to determine nutrition status. A clear clinical and statistical association between BCM and SGA rating was apparent with greater mean BCM for well nourished, compared with the moderately malnourished

patients (33.4 ± 7.3 vs. 26.3 ± 6.3 kg). This association remained significant for females, with a similar trend for males when the relationship was examined by gender. The trend was not statistically significant for males, which may be partially explained by the small sample due to the relatively low rate of malnutrition for males in this sample (Table 2).

Recently, concerns about the limitations of the SGA have been raised by two reports in HD population due to misclassification of nutrition status and inability to detect the degree of malnutrition in HD compared with the respective gold-standard measures^{10, 25}. Due to its broad rating system, it is important to recognise the potential limitations associated with using the SGA rating alone to determine allocation of nutrition resources in settings of Stage IV and V CKD patients²².

The prevalence of malnutrition in this study was similar to a number of recent studies in Stage IV CKD^{16, 17}. In addition, the rate of malnutrition of 19.6% is comparable to recent Australian studies in HD patients^{22, 26}.

The prognostic significance of serum albumin and C - reactive protein (CRP) is well-recognised in Stage V CKD^{7, 27}. Although the presence of low albumin and/or a raised CRP strongly influences outcome of CKD patients, it is likely this is independent of nutrition status. In this study, there appeared no relationship between nutrition status (by SGA or BCM) and albumin or CRP. Whilst it is recognised inflammation and hypoalbuminemia occur in the presence of risk factors for developing malnutrition, such as anorexia and hypermetabolism, in this case, these biochemical parameters were not reliable for the direct assessment of nutrition status.

TBK is considered the gold standard body composition index for assessing BCM, the body's metabolically active tissues²⁸. The method of whole body counting of ⁴⁰K has been shown to be a valid technique in PD patients as in the healthy population^{29, 30}. Potassium is the major intracellular cation, with 98% of the body's potassium contained in the intracellular compartment, it can represent BCM with high precision, enabling the identification of nutrition status that is not hindered by fluid or electrolyte imbalance^{28, 29}.

Previous investigations of TBK in CKD identified malnutrition by depleted TBK compared to TBK from prediction equations³⁰⁻³³ or healthy controls³⁰. In a 7-year prospective study, Dolson *et al* (2003) showed a significant decrease in survival for HD patients with 'depleted' vs 'normal' TBK³¹. Johansson *et al* (1998) in a prospective investigation in PD patients, revealed a small, yet significant progressive loss of TBK for patients stable on PD treatment over 3 years³². To date, validity testing of alternate methods such as bio-impedance analysis (BIA) and dual-energy X-ray absorptiometry (DEXA) to TBK to estimate BCM has been restricted to healthy populations^{34, 35} and other clinical conditions³⁶, however, these methods are contraindicated in CKD, particularly where fluid abnormalities exist^{28, 30}. To the author's knowledge, this is the first paper to investigate BCM from TBK in relation to the SGA and highlights the strong and clinically significant difference in BCM features of malnourished patients identified by SGA in pre-dialysis.

The second objective of this study was to investigate performance of alternate SGA-based tools. The relationship between 7-point SGA and BCM, was not significant

($p=0.267$). When graphing 7-point SGA with BCM, there was an increase in mean BCM from lower rating of 3 to the highest rating of 7. This increase was not linear, and appeared to be a 2-stage pattern, where the rating of “5” appeared to be the threshold between well nourished (>5) and malnourished with depleted BCM (<5). This is in agreement with the recent SGA validation study in HD patients, where the mean of the objective parameters, BMI and albumin were stable from SGA 5 to 7, and only significantly lower values were seen for objective markers in categories 3 and 4³⁷. This investigation supports dichotomising the ratings of 7-point SGA to well-nourished (rating 6 and 7), and malnourished (<5)⁶. Therefore, the 7-point SGA does not distinguish nutrition status better than the original SGA rating for the cross-sectional assessment of nutrition status.

Both the MIS and the PG-SGA score increased to the same extent with decreasing nutrition status showing an identical, yet weak relationship with BCM and a similar distribution of scores with the SGA categories. They therefore appear to be measuring nutritional status to a similar degree. Considering dialysis vintage was not scored as part of the MIS assessment, it is possible to see a higher scoring MIS in dialysis populations. In HD, the MIS tool predicts poor clinical outcome (mortality and hospitalisation)^{9, 38}. Previous investigations indicate the PG-SGA score has a high inter-rater reliability (oncology), sensitivity and specificity when compared with SGA classification for both oncology and HD populations^{22, 39, 40}. Although the relationship between BCM and these scored tools approached borderline statistical significance ($p=0.06$), given the weak correlation ($r=-0.27$), MIS and PG-SGA are also not considered to be ideal for cross-sectional nutrition status assessment.

A limitation of this study is its cross-sectional design. The advantage of the modified SGA-based tools is the potential to be more sensitive to small changes in nutritional status. This particular paper represents the preliminary results of an intervention study, where prospective change in nutrition status, according to the above assessment tools, and the gold-standard BCM measure is to be investigated.

Conclusion: SGA in its original form most accurately delineated malnutrition by depleted BCM and is the most appropriate tool for cross-sectional assessment of nutrition status, compared with 7-point SGA, MIS and PG-SGA in pre-dialysis CKD patients. The new scored assessment tools warrant a prospective investigation in pre-dialysis as longitudinal measures of nutrition status.

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Table 1: Characteristics of participants and non-participants n=62

	Study participants n = 56		Non-participants n = 8
	TBK group	Participants without TBK	Refused or withdrew before assessment
n	50	6	8
Male:Female %	64:36	50:50	25:75
Age (years) $\bar{X} \pm SD$	71.0 \pm 11.9	67.0 \pm 6.1	66.1 \pm 13.6
GFR (ml/min)	22.0 \pm 6.6	19.8 \pm 8.7	16.2 \pm 5.9
Weight (kg)	72.0 \pm 14.4	92.1 \pm 24.2	63.9 \pm 11.8
BMI (kg/m ²)	26.0 \pm 4.3	32.9 \pm 6.7	23.1 \pm 3.2
SGA %	80:20	83:17	75:25*

*SGA conducted on non-participants that originally consented (n=4)

Table 2: Clinical variables in pre-dialysis CKD patients compared with SGA n=56, and body cell mass n=50.

Variable	SGA A n = 45	SGA B n = 11	P-value
Gender (M:F)	29:16	4:7	0.090
Age (y) $\bar{X} \pm SD$	68.8 \pm 11.7	74.0 \pm 11.1	0.192
BCM (kg) n=50	33.4 (7.3)	26.3 \pm 6.3	0.007
Weight (kg)	76.1 (14.7)	64.8 \pm 20.9	0.042
Weight change (6-mo %)	-0.08 \pm 2.37	-6.24 \pm 4.26	0.004
BMI (kg/m ²)	27.6 \pm 4.5	23.7 \pm 4.6	0.015
Albumin (g/L)	38.9 \pm 4.1	37.7 \pm 6.4	0.431
CRP (mg/L) n=33 Median (range)	3.30 (0-53)	2.10 (0-17)	0.331
GFR (ml/min)	21.8 (7.5)	22.5 (4.33)	0.755

Abbreviations: SGA, Subjective Global Assessment; BMI, Body Mass Index; CRP, C-reactive protein; GFR, Glomerular Filtration Rate

Table 3: Clinical variables in pre-dialysis CKD patients compared with body cell mass n=50.

Variable	Relationship to BCM
Gender (M:F)	t(49)=8.48 p<0.001
Age (y)	-0.202 p=0.159
Weight (kg)	0.609 p<0.001
Weight change (6-mo %)	0.353 p=0.060
BMI (kg/m ²)	0.271 p=0.060
Albumin (g/L)	0.231 p=0.118
CRP (mg/L) n=33 Median (range)	-0.157 p=0.407
GFR (ml/min)	-0.117 p=0.424

Table 4: Nutrition assessment tools in pre-dialysis CKD patients against SGA (n=56) and BCM (n=50)

Assessment tool	SGA A n = 45	SGA B n = 11	P-value	Relationship to BCM
PG-SGA Median (range)	3.0 (0-8)	9.0 (4-15)	<0.001	-0.268 p=0.060
MIS Median (range)	4.0 (0-7)	9.0 (5-12)	<0.001	-0.265 p=0.063
7-pt SGA Score (7-1) %	(7) 32%; (6) 45%; (5) 4%	(5) 11%; (4) 5%; (3) 4%	<0.001	f(4)=1.35 p=0.267

Abbreviations: PG-SGA, Patient-Generated Subjective Global Assessment; MIS, Malnutrition Inflammation Score

Figure

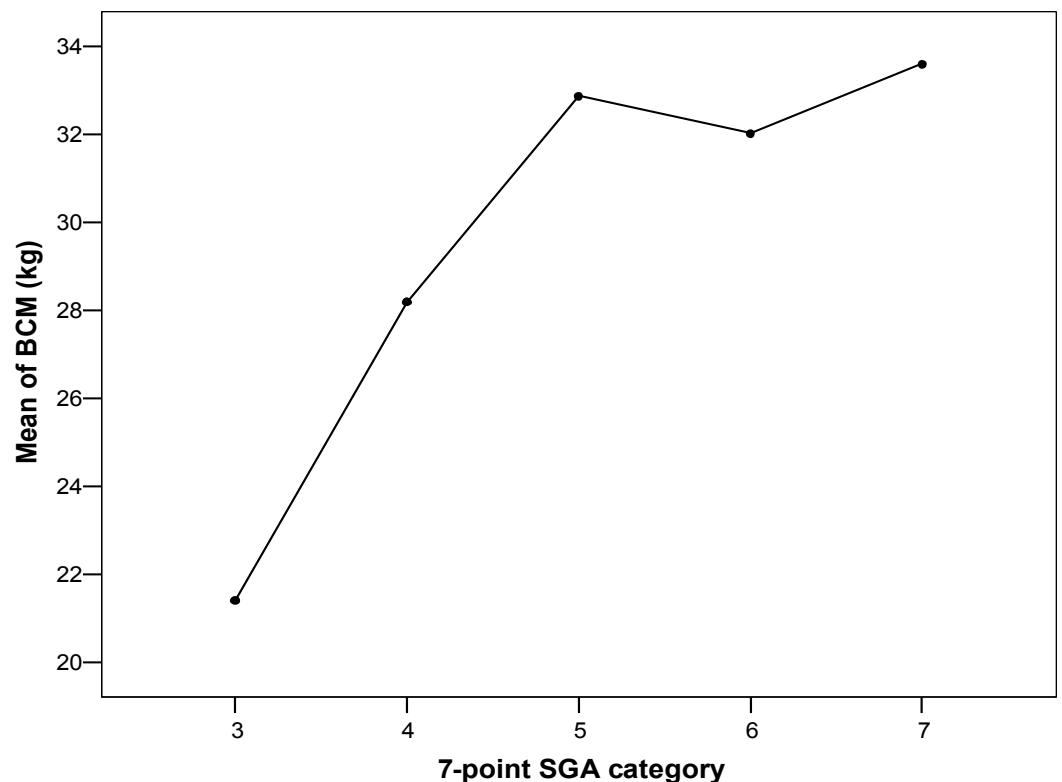


Figure 1 - Mean rating of 7-point Subjective Global Assessment (SGA) against Body Cell Mass (BCM) in CKD patients, n=50.